REMARKS

Reconsideration of this application is respectfully requested.

Claims 22, 23, 28, 29, 32, 34, and 48 have been amended to more specifically recite the components of the pharmaceutical composition. Support for this amendment is found in the specification at, e.g., pages 4-8 and 11-12. Claims 24, 25, and 45-47 have been amended to correct clerical errors. Claims 30, 31, 33, 35, and 44 have been canceled without prejudice or disclaimer. No new matter has been added by way of this amendment. Claims 22-29, 32, 34, 36-43, and 45-48 are pending and at issue.

Enablement Rejection

Claims 22-48 have been rejected for lacking enablement. The Examiner contends that the specification fails to clearly disclose composition components and details of the dose regiment that would enable administration of an effective amount of *Mycobacterium w*.

The rejection is traversed and reconsideration is respectfully requested.

The claims as amended recite that pharmaceutical composition includes heat killed whole cell *Mycobacterium w*, sonicated *Mycobacterium w*, a solvent extract of *Mycobacterium w*, or an enzyme extract of *Mycobacterium w*. Thus, the claims recite the specific form of the *Mycobacterium w*.

With respect to the dosage amounts and route and frequency of administration, applicants respectfully submit that one of ordinary skill in the art could determine proper dosage amounts and routes and frequency of administration of the claimed compositions without undue experimentation. The specification provides significant guidance with respect to these parameters. For instance, the specification provides 10 exemplary 0.1 mL dosage compositions comprising various *Mycobacterium w* preparations. Heat killed whole cell *Mycobacterium w* is used in compositions A-C at a cell count of 0.5×10^9. Compositions D-I recite cellular extracts of *Mycobacterium w* obtained by subjecting 1×10^{10} cells to the various processing steps detailed in the specification at, e.g., pages 11-12. Composition J recites a composition comprising a combination of 0.5×10^7 heat killed whole cell *Mycobacterium w* with a cellular extract of *Mycobacterium w* obtained by subjecting 1×10^3 cells to the processing steps disclosed in the specification at, e.g., pages 11-12.

The route of administration and frequency of administration of the dosage forms are exemplified in the specification. *See* the specification at, e.g., pages 13-14. In the clinical study described in Example 4, for instance, *Mycobacterium w* was administered intradermally at a frequency of once a week for four weeks. Thus the route and frequency of administration are disclosed. *See* the specification at page 13. Further, Example 6 teaches that a 0.1 mL dosage form of *Mycobacterium w* can be administered on a weekly interval. *See* the specification at, e.g., pages 13-14.

Additionally, applicants respectfully submit that the Examiner's contention that the declarations of Dr. Kamar and Dr. Lamperti fail to provide dosage interval or length of treatment is incorrect. The working examples in the application, as discussed in the previously submitted

declarations, show that the claimed invention is enabled. *See*, for example, the table on page 3 of the December 31, 2007 Declaration of Dr. Lamperti. Specifically, the December 31, 2007 Declaration of Dr. Lamperti demonstrates that one of ordinary skill in the art as of the filing date of this application having read the application would understand from the specification that "the appropriate therapeutic dosage is typically 0.1 mL of *Mycobacterium w*, ... the composition could be administered intradermally or by nebulizer approximately once per week, and ... treatment could be continued from four weeks to three months, or longer or shorter depending on the response exhibited by the patient to the treatment." See December 31, 2007 Declaration of Dr. Lamperti at ¶11; *see also* the December 19, 2007 Declaration of Dr. Khamar at ¶4.

Indeed, by the Examiner's own admission, Example 4, contains all of the required information regarding composition components and details of the dose regiment that would enable administration of an effective amount of *Mycobacterium w*. Specifically, the Examiner recognizes that in Example 4, the heat killed *Mycobacterium w* dosage form recited in Example 1A is used "at a dosage of 0.2 mL per week administered intradermally initially followed by a dosage of 0.1 mL per week administered intradermally; both dosages were administered at the interval of one per week. By four weeks patient became asymptomatic..." *See* Office Action at page 2; *See also* December 19, 2007 Declaration of Dr. Khamar at ¶ 4.

Even if, *arguendo*, the specific dose regiments were not presently disclosed, applicants respectfully submit that there are known techniques for determining an effective dose and route and frequency of administration. There is no reason to believe that such techniques would not be successful here.

In view of the foregoing, applicants respectfully submit that undue experimentation would not be needed to practice the current invention and, accordingly the claims are enabled. Thus, applicants respectfully request that this rejection be withdrawn.

Conclusion

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered, and that the pending claims be allowed and the case passed to issue.

If there are any other issues remaining that the Examiner believes can be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

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